Generic Name: Imatinib

Therapeutic Class or Brand Name: Gleevec®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: Imatinib tablets generic

Non-preferred: Gleevec tablets

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 8/15/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through H AND must meet criteria listed under applicable diagnosis

A. Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase:

1. Minimum age requirement: 1 year old.

B. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.

1. Minimum age requirement: 18 years old.

C. Gastrointestinal stromal tumor (GIST) and criterion 1 is met:

1. Minimum age requirement: 18 years old

D. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) or lymphoma and criterion 1 is met:

1. Minimum age requirement: 1 year old.

E. Myelodysplastic/ myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements and criterion 1 is met:

1. Minimum age requirement: 18 years old.

F. Aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown and criterion 1 is met:

1. Minimum age requirement: 18 years old

G. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) in patients who have the FIP1L1-PDGFRa fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown and criterion 1 is met:

1. Minimum age requirement: 18 years old.

H. Unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) and criterion 1 is met:

1. Minimum age requirement: 18 years old.

II. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Non-preferred products (i.e. Gleevec® tablets) require a documented clinical reason containing details as to why generic imatinib is not appropriate or is contraindicated.

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Doses are limited to 800 mg per day. The quantity is limited to a maximum of a 30-day supply per fill.

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix

N/A

References

1. Gleevec. Prescribing information. Novartis Pharmaceuticals Corp.; 2022. Accessed August 15, 2023. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/gleevec_tabs.pdf.
2. NCCN Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia V.1.2022. Accessed April 4, 2022. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.